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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,813	01/03/2002	Lawrence M. Boyd	4002-2734	1340

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EXAMINER

COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,813

Applicant(s)

BOYD ET AL

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005 and 20 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,17,18,20-37,40,41,44-47,50-52,54,56 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,17,18,20-37,40,41,44-47,50-52,54,56 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-7, 9-13, 18, 40, 41, 44-47, 50, 51, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Zdeblick et al. (5,669,909; previously cited).

Zdeblick et al. disclose a pair of interbody fusion devices 10 comprising an elongated generally cylindrical body having end walls 12 and 17, a side wall 16, and a hollow interior chamber 15 between the two ends (Fig. 2). One end 12 has flat discontinuities corresponding to discontinuities 22 in the side wall. The discontinuities allow the device to be nested against another device in a single disc space (see Fig. 6 and col. 7, lines 50-58). The side wall discontinuity extends along a length of the body aligned with the end wall discontinuity. The side wall discontinuity defines a plurality of side wall openings 24,25 to the interior chamber 15. The interbody fusion device 10 is formed of metal (see col. 5, lines 42-47). The outer surface defines threaded bone-engaging portions 18. The device includes a tool-engaging end 13 defining a tool

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engaging hole, e.g. a hex recess (see col. 7, lines 6-10). An osteogenic material is disposed within the chamber (see col. 5, lines 55-59 and col. 7, lines 50-58). Each side wall discontinuity appears to extend over approximately 25% of the circumference of the body (see Attachment A, corresponding to Fig. 4). The side wall discontinuity appears to extend over at least 80% of the length of the body (see Fig. 2). Osteogenic material could be introduced through the openings 24,25. Zdeblick also discloses preparing adjacent vertebrae and placing the devices in the intervertebral space to nest against each other (see col. 7, lines 50-58 and col. 10, line 48 - col. 11, line 51 and Fig. 6). It is also disclosed to pack osteogenic material prior to or after implanting the devices, i.e., "additional bone graft material" where "additional" implies some was added before implantation while the "additional" amount was added "in situ" (see col. 5, lines 55-59 and col. 7, lines 50-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-15, 17, 18, 20-37, 40, 41, 44-47, 50, 51, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (5,669,909; previously cited) in view of Michelson (5,593,409; cited by applicant).

Zdeblick discloses the claimed invention except for the concave side wall and end wall discontinuities. Michelson discloses that flat side walls and concave side walls are functionally equivalent means of allowing two implants to fit within a single disc space (see Figs. 25 and 43, col. 12, line 59 - col. 13, line 3; and col. 15, lines 19-38). It would have been obvious to substitute concave side wall discontinuities for flat side wall discontinuities, in view of Michelson, as this would involve nothing more than the substitution of functionally equivalent means of accommodating two implants in a single disc space, known in the art at the time of the invention. With regard to claims 8 and 27 it also would have been obvious to form the osteogenic material of demineralized bone, a calcium phosphate, bioceramic, bioglass, an osteoinductive factor, or other known materials or mixtures thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 52, 54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brosnahan, III (5,645,598; previously cited).

Brosnahan, III discloses a metal fusion spacer 10 comprising a generally cylindrical elongate body defining a side wall opening into an interior chamber 40 (see Fig. 14 and col. 4, lines 33-41). The first and second ends have a concave discontinuity

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48,50. The side wall includes threads. The end walls are integrally fixed to the side wall. The spacer includes a tool-engaging end having a tool-engaging hole 32. The chamber is filled with an osteogenic material 42 (see col. 5, lines 31-45). The device includes the concave discontinuities to allow it to be closely nested with another implant (see col. 5, lines 46-62). The end walls have a profile defining a discontinuous arc 44,46 extending around at least 180 degrees of the circle and comprise the two concave surfaces 48,50 (see Fig. 14). Brosnahan, III does not explicitly disclose that the opening can be located in the concave surface; however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to position the opening in the concave surface, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Response to Arguments

Applicant's arguments filed 22 February 2005, with regard to Zdeblick (5,669,909) have been fully considered but are not persuasive.

In response to applicant's argument that Zdeblick et al. do not anticipate applicant's invention, it is noted that to be cylindrical, *at least within a broadest reasonable interpretation consistent with the specification*--which is the standard of examination--the implant need only relate to or resemble a cylinder, or a generally circular shape extruded to form a solid, and need not have any other specific characteristics with respect to this limitation. Here, the implant in fact is such a cylinder or at least more closely resembles or relates to the same than it does a cone, since a

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cone shape would need to continue to a pointed end. It is noted that all the disclosures of a reference (i.e. including the figures) must be considered for what they fairly teach a person of ordinary skill in the art. Moreover, the test for interpreting a reference is what the reference as a whole would have suggested to one of ordinary skill in the art. *In re Sheckler*, 168 USPQ 716 (CCPA 1971); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971); *In re Young*, 159 USPQ 725 (CCPA 1968). It is also noted that Applicant's specification must clearly set forth definitions explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01. Applicant also appears to imply, based on Zdeblick et al., col. 2, line 63 - col. 3, line 29, that a spinal implant *must* be tapered to maintain normal spinal curvature. Of course this is not always true, or Applicant's own invention would not be capable of maintaining normal spinal curvature, as it is not tapered. In fact, there are many types of implants including some that are generally cylindrical, some that are generally rectangular, some that have a slight taper, some that do not, and so forth. The device in Zdeblick et al. appears to be a tapered cylindrical implant. The definition above (cited in the previous office action) referring to the term cylindrical as a shape that relates to or resembles a cylinder or as a generally circular shape extruded to form a solid came from Microsoft Bookshelf Basics, which is no longer available to the Examiner. Nevertheless, Examiner maintains that this definition is accurate and within the common knowledge of a person of ordinary skill in

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the art. Similar definitions were found in other dictionaries that also show that under a broadest reasonable interpretation, the term cylindrical requires only that the shape at least **relate to** or be **like** a cylinder; that is, it does not need to actually be a mathematical cylinder. Another definition further broadens the scope of how the term cylindrical can be defined or characterized:

cylindrical: of, **relating to**, or having the shape of a cylinder, especially of a circular cylinder. *The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company (emphasis added). Note: "especially of" implies that it need not necessarily be a circular cylinder.*

cylindrical: pertaining to or shaped **like** a cylinder. Dorland's Illustrated Medical Dictionary (emphasis added).

cylindrical: having the form of a cylinder **or tube**. WordNet ® 2.0, © 2003 Princeton University (emphasis added).

Here, the figures in Zdeblick et al. plainly show a device having a shape that at least *relates to* a cylinder or tube or is *like* a cylinder. Moreover, as Applicant acknowledges, "exactness is a hallmark of the patenting process." Accordingly, it is incumbent upon applicant to define their own invention and claims with sufficient specificity to overcome broadest reasonable interpretations and properly define the meets and bounds of their invention (e.g. define the cylinder as having ends with equal diameters, or the like).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-

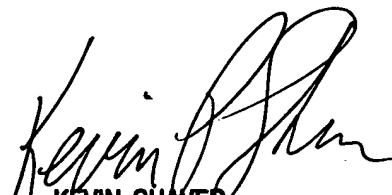
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4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock
26 June 2005



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